

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparative Study Between the effect of cold and warm Intra techal Bupivacaine on shivering in caesarian surgery

Protocol summary

Summary

Patients will randomly assign into two equal groups for spinal anesthesia according to numbers inserted in sealed envelopes. Before performing the spinal anesthesia, patients will be under standard monitoring and receive IV lactated Ringer's solution 10 ml/kg. During anesthesia, oxygen is given, and patients will cover with drapes but not actively be warm. All fluids will warm to 37°C. The patients will divide equally into two groups. (n=39). Group A heavy cold bupivacaine up to 2 milliliter plus 10 micrograms of fentanyl, Group B warm bupivacaine up to 2 milliliter plus 10 micrograms of fentanyl, Spinal anesthesia will perform in sitting position at the L4-5 inter space with a mid line approach by using a 25-gauge Quincke needle. Solutions prepare by another anesthesiologist so that the anesthesiologist performing the spinal block is blind of which drug will be injected. After spinal injection, parturient will be placed supine with left uterine displacement. Shivering and other data

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106271936N6**

Registration date: **2011-06-29, 1390/04/08**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-06-29, 1390/04/08

Registrant information

Name

Abdolreza Najafi Anaraki

Name of organization / entity

Bushehr University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 77 1354 0088

Email address

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Recruitment status

Recruitment complete

Funding source

Bushehr University of Medical Sciences

Expected recruitment start date

2011-07-23, 1390/05/01

Expected recruitment end date

2011-09-23, 1390/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Study Between the effect of cold and warm Intra techal Bupivacaine on shivering in caesarian surgery

Public title

Comparative Study Between the effect of cold and warm Intra techal Bupivacaine on shivering in caesarian surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Parturient (ASA physical status I or II) age between 18 till 40 scheduled for no emergent cesarean delivery under spinal anesthesia and signing the informed consent Exclusion criteria: Contraindications to regional anesthesia; hypersensitivity to amide local anesthetics; history of headache and

severe preeclampsia

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Bushehr University of Medical Sciences

Street address

Siraf avenue

City

Bushehr

Postal code

Approval date

2010-12-08, 1389/09/17

Ethics committee reference number

34454/3/18/20/دپ

Health conditions studied

1

Description of health condition studied

Shivering afer spinal anesthesia

ICD-10 code

O74.9

ICD-10 code description

Complication of anaesthesia during labour and delivery, unspecified

Primary outcomes

1

Description

Post operative shivering

Timepoint

Till 120 minute after surgery

Method of measurement

Observation

Secondary outcomes

1

Description

Nausea and vomiting after surgery

Timepoint

Till 120 minutes after surgery

Method of measurement

Observation

Intervention groups

1

Description

Warm bupivacaine(amid local anesthetic) that hold(in the room) out of refrigerator (%0/5) up to 2 milliliter will be injected Intratechaly once

Category

Prevention

2

Description

Cold bupivacaine(amid local anesthetic) that holdin the refrigerator (%0/5) up to 2 milliliter will be injected Intratechaly once

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Bentolhoda hospital

Full name of responsible person

Dr Najafi Anaraki

Street address

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research committee of medical science

Full name of responsible person

Dr. Asadi

Street address

School of Medicine, Bushehr University of Medical

Sciences
City
Bushehr
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research committee of medical science
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bushehr University of Medical Sciences
Full name of responsible person
Dr. Najafi Anaraki
Position
Assistant professor
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Assistant professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty